

DISPOSITION: May 6, 1954. The defendants having entered pleas of guilty, the court fined the corporation \$1,200 and the individual \$300.

4392. Adulteration and misbranding of Eprinal. U. S. v. 270 Bottles, etc.
(F. D. C. No. 36326. Sample Nos. 30949-L, 30950-L.)

LIBEL FILED: February 19, 1954, Eastern District of Missouri.

ALLEGED SHIPMENT: Sometime prior to January 1, 1951, from Chicago, Ill.

PRODUCT: 270 15-cc. bottles and 150 30-cc. bottles of *Eprinal* at St. Louis, Mo.

Analysis showed that the product, which was represented as "Epinephrine Inhalation," contained 0.5 gram of epinephrine in each 100 cc., whereas the United States Pharmacopeia provides that "Epinephrine Inhalation" contains not less than 0.9 gram of epinephrine in each 100 cc.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Epinephrine Inhalation," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard set forth in such compendium.

Misbranding, Section 502 (a), the label designation "Epinephrine Inhalation U. S. P." and the label statement "Each 100 cc. contains Epinephrine 1 Gram" were false and misleading as applied to an article which contained 0.5 gram of epinephrine per 100 cc.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 25, 1954. Default decree of condemnation and destruction.

4393. Adulteration and misbranding of Special Formula tablets. U. S. v. 44,725 Tablets * * *. (F. D. C. No. 36492. Sample No. 51024-L.)

LIBEL FILED: April 21, 1954, Eastern District of New York.

ALLEGED SHIPMENT: On or about August 25, 1953, from Newark, N. J.

PRODUCT: 44,725 *Special Formula tablets* in 1 drum at Long Island City, N. Y.

Analysis showed that the product contained 50 percent of the declared amount of vitamin D.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 134 U. S. P. units of vitamin D per tablet.

Misbranding, Section 502 (a), the label statement "Each tablet contains: * * * 134 U. S. P. Units Vitamin D" was false and misleading as applied to a product which contained less than 134 U. S. P. units of vitamin D per tablet.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 20, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4394. Misbranding of procaine hydrochloride ampuls. U. S. v. 19 Crates * * *. (F. D. C. No. 36457. Sample No. 48010-L.)

LIBEL FILED: March 23, 1954, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about November 5, 1947, from Savannah, Ga.

*See also Nos. 4381, 4388, 4390-4393.

PRODUCT: *Procaine hydrochloride ampuls.* 19 crates, each containing 325 boxes and each box containing 10 ampuls, at New Orleans, La. Visual examination of the ampuls disclosed that in 33 ampuls out of 60 examined, crystals of the material were sticking to the walls of the ampul and could not be dislodged. Thus, when the top of the ampul was filed off, varying percentages of the procaine hydrochloride would be lost.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Each Ampule Contains: Sterile Procaine HCl 120 mgm." was false and misleading as applied to the article since, when opened and used in the customary manner, a portion of the procaine hydrochloride would adhere to the necks of the ampuls and the quantity delivered would be substantially less than 120 milligrams.

Further misbranding, Section 502 (g), the article purported to be "Sterile Procaine Hydrochloride," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the article was not labeled as prescribed therein since the lot number was not stated on the label of each container.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 5, 1954. Default decree of condemnation and destruction.

4395. Misbranding of apple juice concentrate and chlorophyll formula. U. S. v. 83 Bottles, etc. (F. D. C. No. 36168. Sample Nos. 62671-L, 62672-L.)

LIBEL FILED: December 2, 1953, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about July 15, 1953, by El Rancho Adolphus Products, Inc., from Scranton, Pa.

PRODUCT: 83 1-quart bottles of *apple juice concentrate* and 10 16-ounce bottles and 10 8-ounce bottles of *chlorophyll formula* at St. Louis, Mo., together with a number of leaflets designated "Adolphus Hohensee Gall Stone And Kidney Stone Diet No. 5" and a number of booklets designated "Chlorophyll Therapy By Dr. T. M. Rudolph, Ph. D."

LABEL, IN PART: (Bottle) "El Rancho Adolphus Brand Pure Apple Juice Concentrate Made from Selected Apples Dilute with water, 4 parts to 1 of concentrate. * * * Distributed by * * * El Rancho Adolphus Products, Inc. Hohensee Park, Jermyn, Pa." and "El Rancho Adolphus * * * Chlorophyll Formula Highly purified water-soluble chlorophyll (Sodium Magnesium Chlorophyllin). Concentration 0.2 percent in saline (sodium chloride) solution."

NATURE OF CHARGE: *Apple juice concentrate.* Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was effective in the treatment of gallstones and kidney stones. The article was not effective in the treatment of such conditions.

Chlorophyll formula. Misbranding, Section 502 (a), certain statements in the above-mentioned booklets accompanying the article were false and misleading. The statements represented and suggested that the article was effective in the treatment of high blood pressure, anemia, disturbances of the stomach and intestinal lining, oral infections, chronic osteomyelitis, varicose ulcers, sinusitis, hay fever, rhinitis, otitis media, otitis externa, Vincent's angina, pyorrhea, gingivitis, tonsillitis, laryngitis, pharyngitis, peptic ulcer, gastritis, enteritis, colitis, vaginitis, trichomonas vaginalis, leucorrhea,